

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

DROGUERÍA BETANCES, INC., on behalf
of itself and all others similarly situated,

Plaintiff,

v.

ENDO PHARMACEUTICALS, INC.,
TEIKOKU PHARMA USA, INC.,
TEIKOKU SEIYAKU CO., LTD.
ACTAVIS, INC.,
WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC.,
ANDA, INC.,
ANDA PHARMACEUTICALS, INC., and
VALMED PHARMACEUTICALS, INC.;

Defendants.

Civil Action No. _____

CLASS ACTION
JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Droguería Betances, Inc. (“Betances” or “Plaintiff”), on behalf of itself and all others similarly situated, for its Class Action Complaint (“Complaint”) against Defendants Endo Pharmaceuticals, Inc., Teikoku Pharma USA, Inc., and Teikoku Seiyaku Co., Ltd. (collectively, “Endo”); and Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Anda, Inc., Anda Pharmaceuticals, Inc., and Valmed Pharmaceuticals, Inc. (collectively, “Actavis”) (all collectively, “Defendants”); alleges as follows based on: (a) personal knowledge; (b) the investigation of Plaintiffs’ counsel; and (c) information and belief:

I. NATURE OF THE ACTION

1. This is a civil antitrust action under Sections 1 and 2 of the Sherman Act, 15 U.S.C §§ 1-2, seeking treble damages arising out of Defendants' unlawful exclusion of generic competition from the market for lidocaine topical patch 5%, a product sold by Endo under the brand-name Lidoderm. Prior to the launch of AB-rated generic equivalents, Lidoderm was the only lidocaine topical patch available in the U.S. market and the only topical patch approved by the U.S. Food and Drug Administration ("FDA") for the treatment of post-herpetic neuralgia.

2. Since Lidoderm's approval in 1999, Endo has been able to charge monopoly prices (and earn monopoly profits) on Lidoderm. By 2012, Lidoderm had annual U.S. sales of approximately \$1.3 billion. Because generic versions of brand-name drugs are typically much less expensive than their brand-name counterparts, and because purchasers typically switch rapidly from a brand to a generic once the generic becomes available, Endo's monopoly prices and profits would quickly come to an end once one or more lower-priced generic versions of the product entered the market.

3. On or about November 13, 2009, Actavis sought approval from the FDA to launch a generic equivalent to Lidoderm, which threatened to end Endo's Lidoderm monopoly profits. Actavis was the first to file a substantially complete Abbreviated New Drug Application ("ANDA") seeking approval of a generic equivalent of branded Lidoderm, which made it eligible to sell a generic version of Lidoderm without competition from other ANDA filers for a period of 180 days. Shortly thereafter, Endo sued Actavis, alleging that Actavis infringed U.S. Patent No. 5,827,529 ("the '529 patent"). During that patent suit, Actavis raised a series of defenses including inequitable conduct which seriously threatened to invalidate the '529 patent. The invalidation and/or unenforceability of the '529 patent would not only enable Actavis to start competing with its lower-priced generic Lidoderm product, but would also open the flood gates

to competition from other generic manufacturers (including, but not limited, to a potential less expensive “authorized generic” sold by Endo itself).

4. As detailed below, in order to guarantee a delay to the loss of its monopoly profits from Lidoderm, Endo and Actavis entered into an agreement (the “Agreement”) on May 28, 2012 to forego competition between them for a period of time whereby: (a) Actavis agreed to drop its challenge to the Lidoderm patents and delay entering the market with its less expensive generic equivalent product until September 15, 2013, in exchange for (b) Endo’s agreement to provide for free at least \$96 million worth of branded Lidoderm product (and potentially up to \$240 million worth of free product), which would be delivered to one of three named Actavis wholly-owned and controlled wholesaler subsidiaries who could then resell the branded product at supra-competitive prices. In this context, there was no difference between Endo giving Actavis a check for millions of dollars versus Endo giving Actavis millions of dollars in free product that Actavis (through its wholly-owned and controlled subsidiaries) could resell at the full branded price. This was the functional equivalent of Endo and Actavis unlawfully sharing monopoly profits because Endo gave Actavis a share of the monopoly product volume to sell at monopoly prices, which it did.

5. As an additional inducement for Actavis’ agreement to keep its less expensive product off the market until September 2013, Endo agreed to not launch an authorized generic of Lidoderm to compete with Actavis’ generic equivalent version once it was launched in September 2013. Actavis’ right to 180 days of generic exclusivity as the first ANDA filer for a generic version of Lidoderm did not bar Endo from launching its own generic version of the subject product during Actavis’ exclusivity period (known in the industry as an “authorized generic”). While Actavis’ 180-day exclusivity period gave it the highly lucrative ability to sell

generic Lidoderm without competition from other generic manufacturers seeking to market their products by and through ANDAs, the Defendants recognized that this valuable opportunity could be significantly reduced if Endo chose to launch its own authorized generic during the first 180 days, which is a common strategy in the pharmaceutical industry. An authorized generic is simply the brand product sold under generic trade dress at a cheaper price than the brand. Thus, Actavis obtained a second financial inducement to delay its launch of generic Lidoderm in the form of Endo's illegal agreement to refrain from launching a competing authorized generic until seven and one-half months after Actavis' generic Lidoderm product was on the market.

6. The Federal Trade Commission ("FTC") and other government entities have recognized that the presence of an authorized generic significantly benefits purchasers by both increasing purchaser choices and also creating price competition which reduces generic prices during the first 180 days. By agreeing to not exercise its lawful right to launch an authorized generic until seven and a half months after Actavis' launch, Endo was agreeing to restrain or limit its ability to compete during this period. This would increase Actavis' unit sales and pricing power to the detriment of Lidoderm brand and generic purchasers.

7. Actavis was poised to launch a generic lidocaine patch 5% product ("lidocaine patch") immediately upon receiving final approval from the FDA. Absent the anticompetitive multi-million dollar payoff Actavis received from Endo, Actavis could and would have launched its generic equivalent of Lidoderm much earlier than September 2013 because: (a) it received final approval from the FDA to do so on August 23, 2012; (b) had the resources available to make commercial quantities of this product; and (c) would have launched (i) "at risk" after termination of the 30 month stay, (ii) after prevailing in the patent litigation, or (iii) pursuant to a settlement agreement with Endo that provided for an earlier entry date due to the non-existence

of the payoffs describe here. Furthermore, but for the Agreement, Endo would have launched its own less expensive authorized generic version of lidocaine patches that would have entered the market prior to September 2013 and in direct competition with Actavis' generic product. In turn, once Actavis' first-to-file 180 day exclusivity expired, other generic manufacturers would have also launched generic lidocaine patch product.

8. These earlier generic launches would have resulted in direct purchasers of Lidoderm and generic Lidoderm paying substantially less for their lidocaine patch purchases than they have actually paid. Defendants have shared in the illegal profits reaped from this scheme. Because generic versions of brand-name drugs are typically much less expensive than their brand-name counterparts, and because purchasers typically switch rapidly from a brand to a generic once the generic becomes available, wrongful suppression of generic competition, as occurred here, results in enormous overcharge damages to all purchasers of the drug at issue.

9. Defendants' Agreement has: (a) delayed or precluded the launch of less expensive generic equivalents of Lidoderm in the Territory (as used herein, "Territory" refers to "the United States, including its territories, possessions and the Commonwealth of Puerto Rico," as expressly defined in Section 1(w) of the Agreement); and (b) fixed, raised, maintained or stabilized the price of lidocaine patch products above the levels that would have otherwise existed if subject to competition. Defendants' Agreement was intended to and did, in fact: (a) preclude entry into the market of less expensive generic versions of lidocaine patches in the Territory; (b) fix, raise, maintain or stabilize the prices of lidocaine patch products at supra-competitive levels; (c) permit Endo to monopolize the market for lidocaine patches in the Territory; and (d) allocate 100% of the lidocaine patch market in the Territory to Endo.

II. JURISDICTION AND VENUE

10. This Complaint is filed, and these proceedings are instituted, under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries sustained by Plaintiff and other members of the Class of direct purchasers of Lidoderm resulting from the violation by the Defendants, as hereinafter alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

11. Defendants transact business within this District, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District. Venue, therefore, is appropriate within this District under 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c).

III. PARTIES

12. Plaintiff Droguería Betances, Inc., a corporation organized under the laws of the Commonwealth of Puerto Rico and located at Ave. Luis Munoz Marin, Caguas, Puerto Rico 00725, purchased Lidoderm directly from Defendants during the Class Period as defined below.

13. Defendant Endo Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, sale and marketing of prescription pharmaceuticals used primarily to treat and manage pain.

14. Defendant Teikoku Seiyaku Co., Ltd. is a Japanese corporation, with its principal place of business at 567 Sanbonmatsu Higashikagawa, Kagawa 769-2695, Japan. Teikoku Seiyaku is a special pharmaceutical company that develops and makes enhanced pharmaceutical

products based on its transdermal drug delivery technologies. Teikoku Seiyaku's drug delivery technologies include the technology used in the Lidoderm patch.

15. Defendant Teikoku Pharma USA, Inc. is a California corporation, having a principal place of business at 1718 Ringwood Avenue, San Jose, California. Teikoku Pharma USA is a wholly-owned subsidiary of Teikoku Seiyaku Co., Ltd. On information and belief, Endo Pharmaceuticals Inc., Teikoku Pharma USA, Inc., and Teikoku Seiyaku Co., Ltd. are involved in a marketing enterprise that covers the distribution and marketing of Lidoderm in the U.S. *See* <http://www.reuters.com/article/2010/01/19/endopharma-idUSSGE60I0H220100119>. These entities have acted as a singular entity with respect to the material provisions and performance of the reverse payment Agreement with Actavis, which refers to Endo Pharmaceuticals, Inc., Teikoku Pharma USA, Inc., and Teikoku Seiyaku Co., Ltd. collectively in provisions relating to the grant of patent licenses to Actavis, the agreement not to launch a competing authorized generic during Actavis's generic exclusivity period, and the obligation to deliver free branded Lidoderm product to Actavis prior to any generic launch.

16. Defendant Actavis, Inc. is a corporation organized and existing under the laws of Nevada, with its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054.

17. Defendant Watson Pharmaceuticals, Inc. is a corporation organized under the laws of the state of Nevada, with its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

18. Defendant Watson Laboratories, Inc. is a corporation organized under the laws of the state of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, California

92880. Watson Laboratories, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., which is now Actavis, Inc.

19. Defendant Anda, Inc. is a corporation organized under the laws of the state of Florida, with its principal place of business at 2915 Weston Road, Weston, FL 33331. Anda, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., which is now Actavis, Inc.

20. Defendant Anda Pharmaceuticals, Inc. is a corporation organized under the laws of the state of Florida, with its principal place of business at 6500 Adelaide Court, Groveport, OH 43125. Anda Pharmaceuticals, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., which is now Actavis, Inc.

21. Defendant Valmed Pharmaceuticals, Inc. is a corporation organized under the laws of the state of New York, with its principal place of business at 300 Alt Blvd., Grand Island, NY 14072. Valmed Pharmaceuticals, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., now Actavis, Inc.

22. Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Anda, Inc., Anda Pharmaceuticals, Inc., and Valmed Pharmaceuticals, Inc. are collectively referred to herein as "Actavis." Actavis is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

23. The actions taken by Defendants as described in this Complaint are part of, and were taken in furtherance of, the unlawful scheme alleged herein. These actions were authorized, ordered, and/or done by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' affairs (or the affairs of Defendants' predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants.

IV. CLASS ACTION ALLEGATIONS

24. Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a class defined as follows:

All persons or entities in the Territory who, at any time during the Class Period of August 2012 until the effects of Defendants' conduct cease, purchased branded or generic versions of Lidoderm from any named Defendant (the "Class"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

25. Members of the Class are so numerous that joinder is impracticable. While the exact number of Class members is unknown to Plaintiff, the members of the Class are widely dispersed throughout the Territory. Furthermore, the Class is readily identifiable from information and records in the possession of Defendants.

26. Plaintiff's claims are typical of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of the Defendants; *i.e.*, they have paid artificially inflated prices for lidocaine patches and were deprived of the benefits of competition from less expensive generic versions of Lidoderm as a result of Defendants' wrongful conduct.

27. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

28. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, particularly class action antitrust litigation in the pharmaceutical industry.

29. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because the Defendants have

acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

30. Questions of law and fact common to the Class include:

- a. whether the conduct alleged herein constitutes a violation of the antitrust laws;
- b. whether Defendants conspired to suppress generic competition in the market for lidocaine topical patches;
- c. whether Endo paid Actavis consideration under the Agreement;
- d. whether the consideration Endo gave to Actavis was for a purpose other than prolonging Endo's monopoly in the market for lidocaine patches;
- e. whether the Agreement unlawfully precluded generic competitors not subject to the Agreement from entering the market for lidocaine patches;
- f. whether the Defendants' conduct harmed competition in the market for lidocaine patches;
- g. whether Endo possessed market or monopoly power over the market for lidocaine patches;
- h. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and
- i. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of its direct purchaser customers and if so, the appropriate measure of damages.

31. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of

similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

32. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. REGULATORY AND ECONOMIC BACKGROUND

33. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392), a manufacturer who creates a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application (“NDA”). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents.

34. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman Act (“Hatch-Waxman”).

35. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application (“ANDA”).

36. The ANDA is allowed to rely on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA if it is able to demonstrate

that the proposed generic drug is “bioequivalent” to the corresponding brand drug, meaning it delivers the same amount of active ingredient into the body at the same rate as does the brand.

37. As a counter-balance, Hatch-Waxman streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided the brand-name manufacturer with an opportunity to obtain what is essentially a preliminary injunction, in the form of a 30-month stay of FDA approval of generic manufacturer’s ANDAs.

38. When the FDA approves a brand-name manufacturer’s NDA, it publishes in a publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as the “Orange Book”) any patents which, according to information supplied to the FDA by the brand-name manufacturer: (1) claim the approved drug or its approved uses; and (2) for which “a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1); 21 U.S.C. §355(j)(7)(A)(iii). The FDA does not verify the information supplied by the brand-name manufacturer, but relies completely on the accuracy and truthfulness of applicant’s representations. After an NDA is approved, the brand-name manufacturer may also list other new patents in the Orange Book as related to the NDA, if the brand-name manufacturer similarly certifies that the new patents meet the listing criteria.

39. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not violate any patent listed in the Orange Book as claiming the brand-name drug.

40. Under Hatch-Waxman, a generic manufacturer’s ANDA must contain one of four certifications:

- a. that no patent for the brand-name drug has been filed with the FDA (a “paragraph I certification”);

- b. that the patent for the brand-name drug has expired (a “paragraph II certification);
- c. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a “paragraph III certification”); or
- d. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer’s proposed product (a “paragraph IV certification”).

21 U.S.C. §355(j)(2)(A)(vii).

41. Alternatively, in the case of a method-of-use patent, an ANDA may assert that the patent is inapplicable to the use (commonly referred to as the “indication”) for which the drug product will be marketed (commonly called a “section viii statement”).

42. The FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. §355(j)(5)(A). In the case of a paragraph I or II certification, the ANDA will be given final approval as soon as it satisfies the necessary showings of safety and efficacy. 21 U.S.C. §355(j)(5)(B)(i). In the case of a paragraph III certification, the ANDA cannot receive final approval until expiration of the relevant patent(s) even if the ANDA applicant has previously satisfied the necessary showings of safety and efficacy. 21 U.S.C. §355(j)(5)(B)(ii).

43. If a generic manufacturer files a paragraph IV certification that the listed patent is invalid or will not be infringed, it must promptly give notice to both the NDA owner and the owner of the patent(s) at issue. The filing of an ANDA with a paragraph IV certification gives rise to cause of action for patent infringement. 35 U.S.C. § 271(e)(2)(A). If the patent owner initiates an infringement action against the ANDA filer within 45 days, then the FDA may not grant final approval to the ANDA until the earlier of either (a) 30 months or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer’s

ANDA. 21 U.S.C. §355(j)(5)(B)(iii). If, however, the patent owner fails to initiate a patent infringement action within 45 days after receiving notice of the generic manufacturer's paragraph IV certification, then the FDA may grant final approval to the generic manufacturer's ANDA as soon as the necessary safety and efficacy requirements have been demonstrated. Accordingly, the timely filing of an infringement action provides the patent owner with the equivalent of an automatic preliminary injunction for 30 months. Prompt disposition of such an action, however, as through a motion for summary judgment, may mean more rapid approval for a generic manufacturer subject to such a stay.

44. To encourage generic manufacturers to challenge branded drug patents and/or to design around them, Hatch-Waxman grants the first paragraph IV ANDA filer a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand-name drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D).

45. Typically, AB-rated generic versions of brand-name drugs are priced significantly below the brand-name counterparts. Because of the price differentials, and other institutional features of the pharmaceutical market, AB-rated generic versions are rapidly and substantially substituted for their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease significantly because of competition among the generic manufacturers, and because the loss of sales volume by the brand-name drug to the corresponding generics is dramatic.

46. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (*i.e.*, Hatch-Waxman) and most state legislatures (*i.e.*, Drug Product Selection laws, or "DPS laws"), pharmacists may (and, in most states, must)

substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing doctor. Indeed, both Congress and the state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously: (a) engaging in the type of heavy promotion or “detailing” typically done by brand-name manufacturers; and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

47. Generic competition enables direct purchasers to: (a) purchase generic versions of brand-name drugs at substantially lower prices; and/or (b) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug which competes with the brand-name drug, and therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales. Consequently, brand-name drug manufacturers have a strong incentive to use various tactics, including the tactics alleged herein, to delay the introduction of AB-rated generic competition into the market.

VI. FACTUAL ALLEGATIONS

A. Actavis’ ANDA and Endo’s Patent Infringement Suits

48. On March 19, 1999, the FDA approved a New Drug Application, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), for Lidoderm, an adhesive patch product that contains lidocaine in the amount of 5%, for the relief of pain associated with post-herpetic neuralgia (“PHN”).

49. Approximately 500,000 cases of herpes zoster (a.k.a. “shingles”) occur in the Territory each year. The most common complication of herpes zoster is PHN. This disorder is

characterized by pain along the cutaneous nerve region of a previous herpes zoster flare-up that persists for more than 30 days after the lesions have resolved. Approximately 20% of patients with herpes zoster will experience this complication.

50. Teikoku Pharma USA, Inc., a wholly-owned subsidiary of Teikoku Seiyaku SCo., Ltd. (collectively, "Teikoku"), is currently the owner of and entity responsible for the Lidoderm Patch NDA.

51. Endo Pharmaceuticals, Inc. has the exclusive right to market and distribute the Lidoderm Patch in the Territory and sells the product under the authority of Teikoku's NDA.

52. Prior to the FDA approval of Lidoderm, on October 27, 1998, the PTO issued Patent No. 5,827,529 ("the '529 patent"), entitled "External Preparation for Application to the Skin Containing Lidocaine". The '529 patent expires October 27, 2015.

53. Following the issuance of the '529 patent, Teikoku submitted information regarding the '529 patent to the FDA for listing in the Orange Book with respect to Lidoderm. The FDA thereafter listed the '529 patent in the Orange Book with respect to Lidoderm. Endo Pharmaceuticals, Inc. is the exclusive licensee of the '529 patent.

54. On November 13, 2009, Actavis submitted ANDA No. 20-675 to the FDA, seeking approval to market a generic equivalent of the lidocaine topical patch.

55. On or about January 14, 2010, Actavis notified Teikoku that it had filed ANDA No. 20-675. Actavis' notice letter included a paragraph IV certification that the commercial manufacture, use and/or sale of its generic Lidoderm product would not infringe any valid claim of the '529 patent.

56. As the first-filer of an ANDA for generic Lidoderm, Actavis is entitled to market its generic Lidoderm for 180 days free of competition from other ANDA-based generic

Lidoderm products. This exclusivity does not, however, protect Actavis from competition from a less expensive authorized generic version of Lidoderm, as sold by Endo or a licensee of Endo.

57. On February 19, 2010, Endo sued Actavis in the United States District Court for the District of Delaware (docketed as 10-cv-00138), alleging that Actavis' filing of its ANDA infringed the '529 patent. Endo's infringement suit triggered a 30-month stay that prohibited the FDA from granting Actavis final approval to launch a generic equivalent of Lidoderm until the earlier to occur of: (1) a final judgment that the '529 patent was invalid, unenforceable, and/or not infringed; or (2) July 14, 2012. Actavis counterclaimed, seeking Declaratory Judgment that: (1) the '529 patent was invalid; (2) Actavis' proposed generic product did not infringe the '529 patent; and (3) the '529 patent was unenforceable for inequitable conduct.

58. Actavis' success in litigation involving the '529 patent would not only have enabled Actavis to start competing with its lower-priced generic Lidoderm product, but would also open the flood gates to competition from other generic manufacturers (including, but not limited, to a potential authorized generic sold by Endo). Because generic versions of brand-name drugs are typically much less expensive than their brand-name counterparts, and because purchasers typically switch rapidly from a brand to a generic once the generic becomes available, Endo's monopoly prices and profits would have quickly come to an end once Actavis or other lower-priced generic versions of the product entered the market.

59. In 2012, Endo sold over \$1.3 billion worth of Lidoderm, accounting for almost 31% of Endo Pharmaceuticals, Inc.'s sales revenue that year. During this period, Endo possessed the market power to charge high prices on Lidoderm without losing customers, and it used its market power repeatedly, raising prices even in the face of flat costs, while simultaneously increasing its sales volume.

60. Endo, fearing generic competition and determined to protect its monopoly for Lidoderm, decided to obtain additional patent protection for Lidoderm. In November 2009, Endo Pharmaceuticals, Inc. obtained an exclusive license for three additional patents, Patent No. 5,741,510 (“the ‘510 patent”), Patent No. 6,096,333 (“the ‘333 patent”) and Patent No. 6,096,334 (“the ‘334 patent”). The ‘510 patent, the ‘333 patent, and the ‘334 patent (collectively, “the Rolf patents”) are all part of a single patent family. Endo Pharmaceuticals, Inc. subsequently became the owner and assignee of the Rolf patents. The Rolf patents each expire on March 30, 2014.

61. Although Endo Pharmaceuticals, Inc. obtained an exclusive license under the Rolf patents in November 2009, it wasn’t until October 2010, and well after the filing of Actavis’ ANDA No. 20-675 that Endo Pharmaceuticals, Inc. granted Teikoku a sublicense under the ‘510 patent to make and sell prescription pain medicines and treatments that contain 5% lidocaine, in a patch dosage form, including Lidoderm. Promptly thereafter, Teikoku submitted the ‘510 patent to the FDA for listing in the Orange Book with respect to Lidoderm despite the fact that it claimed in a prior litigation that the ‘510 patent was invalid and not infringed by the branded Lidoderm product. See *Lectec Corporation v. Chattem, Inc., et al.*, Case No. 08-00130, U.S.D.C., E.D.Tx., Doc. No. 20, filed 09/30/2008.

62. Teikoku did not submit to the FDA information regarding the ‘333 patent or ‘334 patent for listing in the Orange Book with respect to the Lidoderm Patch.

63. Pursuant to CFR § 314.94(a)(12)(vi), Actavis was not required to file any certification, including paragraph IV certification, to the ‘510 patent, and Actavis did not do so.

64. On June 27, 2011, Actavis obtained a favorable claim construction ruling on the ‘529 Patent in the pending infringement suit and, as a result, was poised to prevail in the litigation based on a finding of non-infringement and/or obviousness.

65. Two days later, on June 29, 2011, Endo Pharmaceuticals, Inc. filed a patent infringement lawsuit against Actavis in the United States District Court for the District of Delaware (docketed as 11-cv-00575), alleging that Actavis had infringed the Rolf patents. Actavis counterclaimed, seeking Declaratory Judgments that the Rolf patents were invalid and/or unenforceable and that Actavis' proposed generic product did not infringe the Rolf patents. On information and belief, Actavis' defenses and counterclaims were strong and, absent a settlement, Actavis was likely to prevail in the litigation on the Rolf patents.

66. From February 6-14, 2012, a bench trial was held before Hon. Gregory M. Sleet in the District of Delaware in relation to the '529 patent (10-cv-00138). Actavis vigorously argued that the '529 patent was invalid and/or unenforceable due to inequitable conduct and that Actavis' ANDA product would not infringe the '529 patent. By the end of the trial, it was clear that the only way Endo could prevail on its infringement claim was by recycling arguments that the court had previously rejected in the June 2011 claim construction ruling.

B. Actavis' and Endo's Illegal Market Allocation Scheme

67. After the bench trial, and while a decision from the court was still pending, Endo and Actavis entered into the Agreement, whereby Endo paid Actavis substantial consideration for Actavis' agreement to: (a) drop its challenge to Endo's Lidoderm patents and (b) to refrain from selling a lower-priced generic version of Lidoderm until September 15, 2013. In addition, Endo agreed not to launch an authorized generic version of Lidoderm (or to grant a license to anyone else to sell an authorized generic) for a period of seven and one-half months after Actavis entered the market. The Agreement allowed Endo to avoid the loss of its Lidoderm patents and preserve its monopoly profits on Lidoderm sales.

68. On May 28, 2012, Endo and Actavis consummated the settlement of the ‘529 and the Rolf patent litigations, pursuant to which Actavis agreed drop its challenges to the ‘529 and Rolf patents and to refrain from launching a generic equivalent of Lidoderm until September 15, 2013. The Agreement specifically provides:

Subject to Section 2(d), Watson agrees, on behalf of itself and its Affiliates, that, prior to the Start Date, it and its Affiliates shall not directly or indirectly market, offer to sell, sell, have sold, import, manufacture or have manufactured in the Territory any of Watson’s Generic Product. Watson acknowledges and agrees that each of Endo and Teikoku would be irreparably harmed should Watson breach this Section 2(e). Nothing in this Agreement shall prohibit or preclude Watson from exercising its rights under 35 U.S.C. § 271(e)(1). Settlement Agreement at Section 2(e).

“Start Date” means the earliest of: (i) September 15, 2013; (ii) the date of Launch of any Generic Product other than Watson’s Generic Product; or (iii) the last day before Watson would forfeit its 180-day generic drug exclusivity with respect to Watson’s Generic Product due to the operation of 21 U.S.C. 355(j)(5)(D)(ii) as a result of a forfeiture event under 21 U.S.C. 355(j)(5)(D)(i)(I). *Id.* at Section 1(v).

69. In exchange for Actavis’ agreement to drop its challenge to Endo’s patents and delay the launch of its lower-priced generic product, Endo agreed to share with Actavis the monopoly profits that Endo would reap from Lidoderm’s extended market exclusivity through a “Brand Product Supply” provision. The Agreement reads in pertinent part:

Endo/Teikoku shall provide, at no cost, to Watson’s Wholesaler Affiliate Brand Product of value totaling twelve million dollars (\$12,000,000) per month, as measured at the time of each delivery by the then-prevailing Wholesale Acquisition Cost as defined in the Red Book or, if the Red Book is not available, any other comparable U.S. price listing (“WAC”), on the first business day of each month **beginning January 1, 2013 and ending August 1, 2013 (for a total of eight (8) months) for Watson’s Wholesaler Affiliate’s disposal as provided in Section 3(e). Endo shall provide to Watson’s Wholesaler Affiliate an invoice with respect to such Brand Product, which invoice shall reflect the transfer of Brand Product to Watson’s Wholesaler Affiliate at no cost. Notwithstanding the foregoing, Endo/Teikoku’s obligations under this Section 3(b) shall terminate immediately upon the Launch of any Third Party Generic Product in the Territory. The Brand Product provided to Watson’s Wholesaler Affiliate by Endo/Teikoku**

shall have the same NDC number as the Brand Product sold by Endo. In any month in which Endo/Teikoku has provided to Watson's Wholesaler Affiliate any Brand Product under this Section 3(b), and in which a Third Party has Launched a Generic Product in the Territory, Watson shall either (i) return to Endo a pro rata quantity of the Brand Product delivered by Endo/Teikoku during such month, or (ii) reimburse Endo in cash for the value of the Brand Product (based on the WAC measured at the time of delivery by Endo/Teikoku to Watson's Wholesaler Affiliate), in either case for the pro rata portion of the month on and after such Launch computed as the product of (A) (x) in the case of a return of Brand Product to Endo under clause (i), the quantity of Brand Product delivered by Endo/Teikoku during such month, or (y) in the case of a cash reimbursement to Endo under clause (ii), the value of the Brand Product delivered by Endo/Teikoku, and (B) the number of days in the month on and after such Launch divided by (C) the total number of days in the month. Such return or reimbursement shall be made by Watson to Endo within five (5) business days of the date of the Launch of a Generic Product in the Territory. Settlement Agreement at Section 3(b), (Emphasis added).

The Brand Product supplied by Endo/Teikoku to Watson's Wholesaler Affiliate under Sections 3(b) through (d) may be resold solely by Watson's Wholesaler Affiliate to Third Parties for use solely in the Territory on pricing and other terms determined by Watson's Wholesaler Affiliate in its sole discretion, provided that neither Watson nor any of its Affiliates (including its Wholesaler Affiliate) shall sell, distribute or dispose of Branded Product in any manner that would constitute a Bundled Sale. Watson agrees that its Wholesaler Affiliate will honor all Endo price-related contracts as communicated to all Endo wholesalers from time to time in the ordinary course of business, provided that the price related contracts do not impose any requirements on Watson's Wholesaler Affiliate that would be inconsistent with requirements imposed upon other Lidoderm® wholesalers, and further provided that such price-related contracts shall not conflict with the terms of this Agreement. Watson shall comply with all Applicable Laws in connection with its resale of the Brand Product. Settlement Agreement at Section 3(e), (Emphasis Added).

70. The parties expressly provide in the Agreement at Section 1(a) that "Affiliate" means an entity that "directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with a given entity." Anda, Inc., Anda

Pharmaceuticals, Inc., and Valumed Pharmaceuticals, Inc., all wholly-owned subsidiaries of Actavis, were designated as Watson's Wholesaler Affiliates under the Agreement. These entities thus operated as a single entity for purposes of carrying out the terms and purposes of the anticompetitive Agreement.

71. Actavis' agreement to honor all Endo price-related contracts effectively prevented Actavis from selling any of the branded product delivered pursuant to the Agreement at prices appreciably lower than the supra-competitive prices charged by Endo for the brand product. In fact, Anda, Inc., Anda Pharmaceuticals, Inc., and Valumed Pharmaceuticals, Inc. (Actavis' wholly-owned subsidiaries designated as Watson's Wholesaler Affiliates under the Agreement) maintained the supra-competitive prices for branded Lidoderm throughout the term of the Agreement.

72. The Agreement further provided that if Actavis did not receive FDA approval of its generic Lidoderm product by January 1, 2014, Endo would make up to twelve additional monthly payments to Actavis in the form of \$6,666,667 in free-of-charge Branded Product. The monthly payments would terminate if Actavis received FDA approval or if a third party launched a generic product during that period.

73. In addition, the Agreement provided that if Actavis did not receive FDA approval of its generic Lidoderm product by January 1, 2015, Endo would make up to nine additional monthly payments to Actavis in the form of \$7,111,111 in free-of-charge Branded Product. These monthly payments would terminate the month before the termination date of the '529 patent, or would terminate earlier if Actavis received FDA approval or if a third party launched a generic product during that period.

74. The compensation to Actavis under the Agreement in the form of at least \$96 million dollars-worth, and possibly as much as \$240 million dollars-worth, of free-of-charge Brand Product far exceeded Endo's avoided litigation costs and, as the Agreement expressly provided, was consideration for the settlement of the litigation and independent of any other transaction:

Endo/Teikoku and Watson agree that the Brand Product provided by Endo/Teikoku to Watson's Wholesaler Affiliate hereunder is a good-faith, bargained-for resolution of the claims at issue in the Litigation. The Brand Product provided hereunder is not contingent on any past or future purchase of any product from Endo or Teikoku by Watson or any of its Affiliates. Agreement, Section 3(i).

75. Endo also agreed not to launch an authorized generic version of Lidoderm (or to grant a license to anyone else to sell an authorized generic) for a period of seven and one-half months after Actavis entered the market. The Agreement reads:

License. Subject to the terms and conditions of this Agreement, Endo/Teikoku hereby grant to Watson a non-exclusive (other than pursuant to Section 2(b)), royalty-bearing, non-transferable (other than pursuant to Section 21) and non-sublicensable (other than pursuant to Section 2(c)) license to the Licensed Patents to make, have made, import, use, sell, and offer for sale Watson's Generic product in the Territory solely during the License Term.
Settlement Agreement at Section 2(a).

AG Product. The license granted pursuant to Section 2(a) shall be partially exclusive for a period of time in that **Endo/Teikoku and their respective Affiliates shall not market or sell a Generic Product, or authorize or license a Third Party to market or sell and AG Product at any time before the earlier of (i) seven and a half (7.5) months from the Start Date, and (ii) the Launch of any Third Party Generic Product in the Territory.**
Settlement Agreement at Section 2(b) (Emphasis Added).

76. A brand company's launch of an authorized generic is extremely damaging to any first-filer generic, such as Actavis, because it results in lost market share (*i.e.*, fewer units sold),

reduced profits because price competition between the generic and authorized generic forces down prices, and a reduction in the generic's long-term "first mover advantage." As the FTC noted in a June 2009 report on authorized generics, "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [authorized generic] enters the market, due to the greater discounting that accompanies the added competition provided by the [authorized generic]."

77. Notably, while a brand company can lower the prices on its brand products instead of launching an authorized generic, that option does not present the same danger to a generic such as Actavis, and does not result in the same savings to purchasers. This is because many states have regulations that either require or strongly encourage pharmacists to automatically fill prescriptions with only an AB-rated generic version of a drug in most situations. Thus, even if an NDA holder (such as Endo) lowers the price of its brand drug, state regulations are a barrier that prevent or impede the branded drug from being used for most prescriptions since it is still considered a "brand" drug. The result is that most of a generic's sales volume is unaffected by a reduction in the brand price and the generic does not feel the competitive pressure to lower its prices in response to a drop in the branded price (in contrast to the situation where a branded company launches an authorized generic). Thus, while an NDA holder can try to compete against a generic drug through various means other than launching an authorized generic, those competitive options are far weaker and do not provide nearly the consumer savings and benefits as the launch of a true authorized generic, which has its own unique NDC number, generic trade dress, generic pricing, and is formally considered a "generic" product in managed care sectors. Consequently, Endo's agreement to restrict its competitive responses to far less effective options was an illegal, anticompetitive agreement by which the

parties agreed to restrict competition that would have undermined Actavis' sales and/or constrained Actavis' prices for up to seven and one-half months after the launch of Actavis' generic, all of which results in overcharges to purchasers.

78. Indeed, in its June 2009 report regarding authorized generics, the FTC expressly concluded that a generic manufacturer might agree to delay the sale of its generic product in exchange for a brand company's agreement (such as the one involved here), to not launch an authorized generic to consumers' detriment:

To prevent this loss of revenue, a generic may be willing to delay its entry in return for a brand's agreement not to launch an authorized generic – that is, a brand's agreement not to compete with the generic through an AG – during the generic's 180 days of marketing exclusivity ... Such agreements can harm consumers ...

A “no authorized generic” reverse payment can actually be more anticompetitive than a cash reverse payment because it creates two levels of harm to competition; not only is generic entry delayed, but when it does ultimately occur, it results in supra-competitive prices because there is no authorized generic on the market to effectuate price competition.

79. According to the FTC report, “Revenues of a sole ANDA generic company during the 180-day exclusivity period drop substantially with [authorized generic] entry, with estimates of the average decline ranging from 47% to 51%.” FTC Rpt. at 3.

80. Under the terms of the Agreement, Actavis agreed to kick back to Endo a share of the increased profits that would result from Endo's agreement not to launch an authorized generic during Actavis' exclusivity period. The Agreement provided for the allocation of profits from the supra-competitive generic pricing during the exclusivity period through a 25% royalty on Actavis sales during the period in which no other generic was on the market:

Beginning with the First Commercial Sale of Watson's Generic Product and until the date of the occurrence of the First Commercial Sale by a Third Party or Endo/Teikoku or their Affiliates of a Generic Product or AG Product in the Territory, Watson shall pay to Endo

royalty payments equal to twenty-five percent (25%) of all Gross Profit of Watson's Generic Product. For the avoidance of doubt, this royalty obligation is terminated entirely on the date of the First Commercial Sale by a Third Party or Endo/Teikoku or their Affiliates of a Generic Product or AG Product in the Territory, so that Watson will owe no royalty as of that first date, other than royalties then accrued but not yet paid. *See* Agreement, Section 3(a).

81. The 25% royalty on profits during the exclusivity period was a small price to pay for a no-authorized-generic covenant from Endo that allowed Actavis to double its sales *and* charge higher prices during that period.

82. Endo's unexplained agreement to pay \$96 to \$240 million, combined with its unexplained agreement to forego its right to launch a competing authorized generic product during the generic exclusivity period:

- (a) suggest that Endo had serious doubts about the patents' validity and/or enforceability against Actavis;
- (b) provide strong evidence that Endo sought to induce Actavis to abandon its challenge to Endo's patents in exchange for a share of Endo's monopoly profits that would otherwise have been lost in the competitive market; and
- (c) suggest that the consideration's objective was to maintain supra-competitive prices to be shared between Endo and Actavis, rather than face what might have been a competitive market.

83. Actavis received final approval to launch its generic Lidoderm product on August 23, 2012. However, in accordance with the Agreement, Actavis did not launch its less expensive generic product at that time, nor did Endo launch its less expensive authorized generic. Rather, Endo continued to enjoy the monopoly profits derived from its market exclusivity and, on January 1, 2013, began to deliver no-cost branded product to Actavis, which Acavis could and did resell at the branded Lidoderm monopoly price. When Actavis finally did launch its AB-

rated generic product in September 2013, Endo complied with the Agreement and did not launch a competing authorized generic. As of the date of filing of this Complaint, the Actavis product remains the only AB-rated generic equivalent to Lidoderm available in the Territory.

84. But for Defendants' ongoing, illegal, anticompetitive conduct, a less expensive generic equivalent of Lidoderm, and a less expensive authorized generic version of Lidoderm would have been available in the Territory far earlier than September 2013.

85. But for Defendants' ongoing, illegal, anticompetitive conduct, Plaintiff and other members of the Class would have paid lower prices for Lidoderm and its generic equivalent long before September 2013. As a result, Defendants, by their conduct, have injured Plaintiff and other members of the Class by causing them to pay hundreds of millions of dollars in overcharges on their purchases of Lidoderm.

VII. ANTICOMPETITIVE EFFECT

86. The Agreement has enabled the Defendants to: (a) preclude the entry of less expensive generic versions of Lidoderm products in the Territory; (b) fix, raise, maintain, or stabilize the price of Lidoderm products; and (c) allocate 100% of the U.S. market for lidocaine patches to Endo.

87. Actavis' ANDA was finally approved by FDA on August 23, 2012. But for the illegal Agreement between Endo and Watson (which included financial inducements to delay the launch of less expensive generic versions of Lidoderm) Actavis would have begun selling a less expensive AB-rated generic version of Lidoderm shortly thereafter. Such sales would have occurred via market entry by Actavis through (a) an agreement between Endo and Actavis which did not include illegal financial inducements to delay generic launch and thus would allow for

market entry prior to September 2013, (b) a victory by Actavis in the patent litigation, or (c) a launch “at risk” by Actavis upon termination of the 30 month stay but before termination of the patent litigation. In addition, upon market entry by Actavis, Endo would have begun selling its own less expensive authorized generic version in direct competition

88. An increasingly competitive market for lidocaine patches would have thereafter emerged as additional generic manufacturers entered the market.

89. Defendants’ unlawful concerted action has delayed or prevented the sale of generic Lidoderm in the Territory, and unlawfully enabled Endo and Actavis to sell Lidoderm at artificially inflated, supra-competitive prices. But for Defendants’ illegal conduct, generic competition to Lidoderm would have occurred already because one or more of the generic companies would have already entered with its generic version of Lidoderm.

90. The anti-competitive harm in the form of delayed AB-rated and authorized generic entry and restricted generic competition after entry far outweighs the pro-competitive benefits, if any, of the Agreement.

VIII. EFFECT ON INTERSTATE COMMERCE

91. At all material times, Lidoderm, manufactured and sold by Endo, was shipped across state lines and sold to customers located outside its state of manufacture.

92. During the relevant time period, in connection with the purchase and sale of Lidoderm, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

93. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and

interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint were within the flow of, and have substantially affected, interstate commerce.

IX. MARKET POWER AND RELEVANT MARKET

94. At all relevant times, Endo had monopoly power over lidocaine patches because it had the power to maintain the price of the drug it sold as Lidoderm at supra-competitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Lidoderm, with the exception of AB-rated generic versions of Lidoderm.

95. A small but significant, non-transitory price increase for Lidoderm by Endo would not have caused a significant loss of sales.

96. Lidoderm does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Lidoderm.

97. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which lidocaine patches are prescribed. Endo needed to control only Lidoderm and its AB-rated generic equivalents, and no other products, in order to maintain the price of Lidoderm profitably at supra-competitive prices. Only the market entry of a competing, AB-rated generic version of Lidoderm would render Endo unable to profitably maintain its current prices of Lidoderm without losing substantial sales.

98. Lidoderm is unique and not reasonably interchangeable with other therapies for the treatment of post herpetic neuralgia. Prior to the launch of AB-rated generic equivalents in September 2013, Lidoderm was the only topical lidocaine patch available in the U.S. market and the only topical patch approved by the U.S. Food and Drug Administration ("FDA") for the treatment of post-herpetic neuralgia.

99. Endo also sold Lidoderm at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

100. Defendants have had, and exercised, the power to exclude and restrict competition to Lidoderm and AB-rated bioequivalent generics.

101. Without the power to exclude and restrict competition to lidocaine patches (Lidoderm and AB-rated bioequivalent generics), and ability to sell its own branded version of that drug, Lidoderm, at prices well in excess of marginal costs, it would not have been economically rational for Endo to provide Actavis with the herein alleged substantial financial inducements for the purpose of delaying Actavis' launch of its AB-rated generic Lidoderm product.

102. Endo, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

103. To the extent that Plaintiffs are legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, Plaintiffs allege that the relevant market is for lidocaine patches (*i.e.*, Lidoderm and its AB-rated generic equivalents). During the period relevant to this case, Endo has been able to profitably maintain the price of lidocaine patches well above competitive levels.

104. The relevant geographic market is the Territory. At all relevant times prior to Actavis's launch of an AB-rated generic equivalent of Lidoderm in September 2013, Endo's market share in the relevant market was 100%, implying a substantial amount of monopoly power.

**X. FIRST CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2**

105. Plaintiff incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

106. Endo used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend its monopoly power in the lidocaine patch market, as detailed above.

107. The goal, purpose and/or effect of the scheme was to prevent, delay and or minimize the success of the entry of generic lidocaine patch competitors which would have sold generic lidocaine patches in the Territory at prices significantly below Endo's prices for Lidoderm, which would have effectively caused the average market price of lidocaine patches to decline dramatically.

108. The goal, purpose and/or effect of Endo's scheme was also to maintain and extend Lidoderm's monopoly power with respect to lidocaine patches. Endo's illegal scheme to prevent, delay and/or minimize the success of the introduction into the marketplace of any generic version of Lidoderm enabled Endo to continue charging supra-competitive prices for lidocaine patches in the Territory without a substantial loss of sales.

109. As a result of Endo's illegal conduct, Plaintiff and the other members of the Class paid more than they would have paid for lidocaine patches absent such illegal conduct. But for Endo's illegal conduct, competitors would have begun marketing versions of lidocaine patches well before they actually did, and/or would have been able to market such versions more successfully.

110. If manufacturers of generic lidocaine patches entered the market and competed with Lidoderm in a full and timely fashion, Plaintiff and the other members of the Class members would have substituted lower-priced generic lidocaine patches for the higher-priced

brand-name Lidoderm for some or all of their lidocaine patch requirements, and/or would have received lower prices on some or all of their remaining Lidoderm purchases.

111. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Lidoderm directly from Endo. As a result of Endo's illegal conduct alleged herein, Plaintiff and the other members of the Class were compelled to pay, and did pay, artificially inflated prices for their lidocaine patch requirements. Plaintiff and the other members of the Class paid prices for lidocaine patches that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower priced generic lidocaine patches instead of expensive brand-name Lidoderm; (2) Class members were forced to pay artificially inflated prices for generic lidocaine patches; and/or (3) the price of branded Lidoderm was artificially inflated by Endo's illegal conduct.

112. Endo's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for lidocaine patches in the Territory, in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.

**XI. SECOND CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2**

113. Plaintiff incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

114. Defendants Endo and Actavis combined, conspired and contracted between and among themselves to unreasonably and unlawfully restrain and monopolize trade and to attempt to monopolize trade with specific intent, and Endo did, in fact, monopolize trade in the Territory in the market for lidocaine patches, and to eliminate competition in the sale of Lidoderm and its generic equivalents in the Territory.

115. Endo and Actavis, their agents and affiliates and co-conspirators, both known and unknown, entered into and engaged in a continuing unlawful trust in restraint of trade and commerce in Lidoderm and its generic equivalents, in violation of the Sherman Act by entering into agreements to extend patent monopolies and to divide markets and allocate customers.

116. The purpose and effect of such agreements was to fix, raise, stabilize and maintain the prices for Lidoderm and its generic equivalents at supra-competitive levels, which increased prices paid by Plaintiff and the Class.

117. During the period covered by this Complaint and thereafter, Plaintiff and the other members of the Class purchased lidocaine patches and will continue to purchase lidocaine patches, and by reason of the alleged violation of the antitrust laws, Plaintiff and the other members of the Class paid more and will pay more for these drugs than they would have paid in the absence of the illegal trust, combination and agreement. As a proximate result thereof, Plaintiff and the other members of the Class have been injured and will continue to be injured in their business and property and have suffered damages in an amount according to proof at trial.

**XII. THIRD CAUSE OF ACTION
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1**

118. Plaintiff incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

119. Beginning in or about May 2012, Endo and Actavis engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of lidocaine patches in the Territory to Endo; (b) prevent the sale of a generic version of lidocaine patches in the Territory until at least September 15, 2013, thereby protecting Lidoderm from any generic competition; and (c) fix the price at which Plaintiff and

the other members of the Class would pay for branded and generic Lidoderm at the higher, branded price.

120. Endo and Actavis also engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, in which Endo agreed to not sell its competing authorized generic version of generic Lidoderm until seven and one-half months after Actavis' generic Lidoderm product was on the market.

121. By entering into these unlawful conspiracies, Endo and Actavis have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. The Agreement is a horizontal market allocation and price fixing agreement between actual or potential competitors and thus is a *per se* violation of Section 1. In the alternative, the Agreement is an unreasonable restraint of trade in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.

122. Plaintiff and the other members of the Class have been injured in their business and property by reason of Endo's and Actavis' unlawful contract, combination and conspiracy. Plaintiff and the other members of the Class have paid more on their purchases of Lidoderm than they would have paid absent Endo's and Actavis' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lidoderm.

123. As a result of Endo's and Actavis' illegal conduct, Plaintiff and the other members of the Class paid more than they would have paid for lidocaine patches, absent Endo's and Actavis' illegal conduct. But for Endo's and Actavis' illegal conduct, competitors would have begun marketing generic versions of lidocaine patches well before September 16, 2013, and/or would have been able to market such versions more successfully.

124. If manufacturers of generic lidocaine patches entered the market and competed with Lidoderm in a full and timely fashion, Plaintiff and the other members of the Class would have substituted lower-priced generic lidocaine patches for the higher-priced brand-name Lidoderm for some or all of their lidocaine patch requirements, and/or would have paid lower prices on some or all of their remaining Lidoderm purchases.

125. During the relevant period, Plaintiff and the other members of the Class purchased substantial amounts of Lidoderm directly from Endo. As a result of Endo's illegal conduct, alleged herein, Plaintiff and the other members of the Class were compelled to pay, and did pay, artificially inflated prices for their lidocaine patch requirements. Plaintiff and the other members of the Class paid prices for lidocaine patches that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic lidocaine patches instead of expensive brand-name Lidoderm; (2) Class members were forced to pay artificially inflated prices for generic lidocaine patches; (3) the price of brand-name Lidoderm was artificially inflated by Endo's and Actavis' illegal conduct; and/or 100% of generic Lidoderm sales in the Territory allocated to Actavis during the first 180 days, if not longer of generic sales.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed class, prays for judgment against all Defendants, jointly and severally, as follows:


1. That the Court adjudge and decree that the Defendants and each of them have violated Sections 1 and 2 of the Sherman Antitrust Act;
2. That the Plaintiff, and all others similarly situated, be awarded damages suffered by reason of these violations and that those damages be trebled in accordance with the law;

3. That the Plaintiff be awarded reasonable attorney's fees and costs;
4. That any and all patents held by Endo with regard to Lidoderm be declared null and void and have no further effect;
5. That any and all rights that Actavis may have under the Hatch-Waxman Act be declared null and void and of no further effect; and
6. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all claims and complaints in this Complaint so triable.

Dated: November 8, 2013



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